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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard J. Zeman

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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/611,652

Applicant(s)

ZEMAN ET AL.

Examiner

San-ming Hui

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8, 10 and 37-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 10, 37-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendments filed December 6, 2004 have been entered.

Claims 1-5, 8, 10, 37-51 are pending.

Applicant's arguments filed December 6, 2004 averring Murphy's failure to teach the limitation recited in claim 37 have been considered, and are found persuasive to withdraw the rejection under 35 USC 102 and 103 over Murphy.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3, 38-39, and 50-51 contain the trademark/trade name "BRL-47672".

Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade

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name is used to identify/describe a  $\beta$ 2-agonist and, accordingly, the identification/description is indefinite.

Response to the arguments

Applicant's arguments citing several scientific journal articles as evidence that "BRL-47672" as well-known in one of ordinary skill in the art is not persuasive. Firstly, BRL-47672 is not a widely acceptable IUPAC name. It is just a code name. Secondly, information from journal articles is not generally considered as "well-known" to one of ordinary skill in the art. If a text-book reference, which states what "BRL-47672" is, is cited, then the Examiner will consider favorably to withdraw the rejection. Examiner would also favorably consider the full chemical name of "BRL-47672" recited in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5, 8, 41-44, and 47-49 are rejected under 35 U.S.C. 102(a) as being anticipated by Murphy et al. (Arch. Phys. Med. Rehabil., 1999;80(10):1264-1267).

Murphy et al. teaches a method of employing salbutamol in dosage of 2mg twice daily in spinal cord injury patients to improve the functional electrical stimulation training

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in these patients (See the abstract and page 1264, col. 1, Subjects and Methods Section).

Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective or treatment utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)". In the instant application, Applicants' failure to distance the proffered claims from the anticipated treatment utility, renders such claims anticipated by the prior inherent use.

Response to arguments with regard to rejection under 35 USC 102

Applicant's arguments filed December 6, 2004 averring Murphy's failure to teach whether salbutamol as treating spinal cord or muscle tissue have been considered, but are not found persuasive. Examiner notes that whether salbutamol is intended to be used to treat muscle tissue or not is not important because salbutamol is administered to patients with spinal cord injury. Such administration reads on the method step recited in the instant claims, i.e., the administration of salbutamol to spinal cord injury patients. Therefore, the resulting effect as recited will be inherently present in the same patients treated with salbutamol, absent evidence to the contrary.

Applicant's arguments filed December 6, 2004 averring the herein recited resulting limitation not being "necessarily present" have been considered, but are not found persuasive. Applicant's reasons are merely based on a possibility that the time of administration may be different from what has been claimed in the instant claims. Examiner notes that there are no positive teachings in Murphy to suggest what the Applicant's speculation as indeed true.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy et al. as applied to claims 1-3, 5, 8, 41-44, and 47-49 above.

Murphy does not expressly teach the dosage of salbutamol as 0.25mg/day per kg body weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the dosage of salbutamol to 0.25mg/day per kg body weight.

One of ordinary skill in the art would have been motivated to adjust the dosage of salbutamol to 0.25mg/day per kg body weight. The optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan.

#### Response to arguments

Applicant's arguments filed December 6, 2004 with regard to rejections under 35 USC 103(a) over Murphy have been considered, but are not found persuasive since the arguments address the same issue as the rejection under 35 USC 102, which have been addressed above.

Claims 1-5, 8, 10, 37-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (US Patent 5,281,607).

Stone et al. teaches a method of treating spinal cord injury and motor degenerating diseases such as ALS, infantile spinal muscular atrophy, and juvenile spinal muscular atrophy by employing  $\beta$ -agonists, including dobutamine, clenbuterol, salbutamol, terbutaline, and fenoterol (See col. 4, lines 14-25, 62-66 and col. 5, line 15). Stone et al. also teaches the dosage of  $\beta$ -agonists employed as 0.01 to 100mg/kg of body weight (See col. 6, line 46).

Stone et al. does not expressly teach the dosage employed as 0.5 to 100 $\mu$ g/kg, 0.5 to 1000 $\mu$ g/kg, 0.04 mg/kg, or 0.25mg/day per kg of body weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the dosage of  $\beta$ -agonists to the herein claimed amount.

One of ordinary skill in the art would have been motivated to adjust the dosage of  $\beta$ -agonists to the herein claimed amount. The optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan, absent evidence to the contrary.

#### Response to arguments

Applicant's arguments filed December 6, 2004 with regard to the Stone in Neuroscience Letter have been considered, but are not found persuasive. The article merely mentions the yohimbine's failure to induce nerve growth factor in rats. It is not



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clear whether salbutamol will have the same effect as yohimbine. Secondly, the rats in the experiments are not having spinal cord or CNS injury. There is no clear teaching away from Stone's article in Neuroscience Letter.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
San-ming Hui  
Primary Examiner  
Art Unit 1617